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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|-------------|----------------------|---------------------|------------------|
| 10/584,801 | 06/28/2006 | Andrew James Francis | 06086 | 3427 |
| 23338 | 7590 | 11/25/2009 | EXAMINER | |
| DENNISON, SCHULTZ & MACDONALD | | | MA, JAMESON Q | |
| 1727 KING STREET | | | | |
| SUITE 105 | | | ART UNIT | PAPER NUMBER |
| ALEXANDRIA, VA 22314 | | | 1797 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 11/25/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|-----------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/584,801 | FRANCIS, ANDREW JAMES |
| | Examiner | Art Unit |
| | JAMESON Q. MA | 1797 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 August 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 31-37, 44, 46 and 52-57 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 31-37, 44, 46 and 52-57 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>20090810</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 31-32, 35-37, 44, 46, and 53-55 rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. (US 2003/0206831) in view of Skukowski (US 4,513,027).

For claim 44, it is noted that a recitation directed to the manner in which a claimed apparatus is intended to be used does not distinguish the claimed apparatus from the prior art, if the prior art has the capability to so perform. Additionally, Stevens discloses a container having a body with an opening, a priority indicator (label 50 is viewed as a priority indicator) on the body which is visible when a lid (see fig. 1) is in place to close the opening.

For claims 31, 44 and 54, Stevens discloses a specimen container and a method of making a specimen container comprising a body with a defined circumference (tube 20), a lid (see fig. 1), and a substantially continuous indicator band extending around the body (label 40 containing barcode information); the band being located on the body of the container prior to a specimen being located within the body of the container.

The band of Stevens is viewed as extending sufficiently around the body and circumference such that it is readily viewable from all sides of the container when the container is placed in a specimen rack.

Stevens does not explicitly disclose the indicator band as colored having a brightness greater than 40% and a saturation greater than 40%.

Skukowski discloses a marking composition which comprises a mixture of colored pigment, preferably red, and white pigment (see abstract). Skukowski discloses that the reddish pigment allows code symbols processed by a visible or infrared code

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indicia scanning system. The pigment can be employed on a non-reflective substrate or on a transparent container (see C1/L33-43).

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the reddish pigment of Skukowski into the indicia code label of Stevens in order to allow the symbols to be effectively processed by a visible or infrared indicia scanning system, as taught by Skukowski.

Modified Stevens does not explicitly disclose that the colored indicator band (or reddish pigment) has a color of brightness greater than 40% and a saturation greater than 40%. Skukowski discloses that the relative amounts of white and colored pigments employed in the compositions depend upon the actual reflectance required as well as the shade of color required. Therefore, as the desired shade of color and reflectance are variables that can be modified, among others, by adjusting said color brightness and saturation, the precise color brightness and saturation would have been considered result effective variables by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed color brightness and saturation cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the color brightness and saturation in the apparatus and method of modified Stevens to obtain the desired balance between the reflectance and the shade of color (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the

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optimum or workable ranges involves only routine skill in the art. (In re Aller, 105 USPQ 223).

For claim 32, Stevens discloses that the indicator band is a second label applied to the body.

For claims 35-37, Stevens discloses that the indicator band includes a human or machine-readable element (see fig. 1: barcode), a removable tag (peel away portion 70), and wherein the removable tag is an adhesive tag.

For claim 46, the priority indicator is integral with the label.

For claim 53, the indicator band is a portion of the label.

For claim 55, the method includes the step of incorporating the indicator band includes applying the label to the body.

5. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. (US 2003/0206831) in view of Skukowski (US 4,513,027) as applied to claims 31-32, 35-37, 44, 46, and 53-55 above, and further in view of Miller et al. (US 6,461,063).

Regarding claim 52, modified Stevens discloses all of the claim limitations as set forth above. However, the reference does not explicitly disclose that the indicator band is a label that is fluorescent.

However, Stevens does disclose that the invention relates to containers of vessels for collecting fluid samples from patients and providing means affixed to the container which can link the containers electronically to the operating stations in a laboratory (see [0001]).

Miller teaches that in applications using barcodes printed on labels (such as mailing applications), it is useful to incorporate additional unique identifying information along with the items to be labeled (see C3/L11-23). Miller also teaches that one method of doing this is to use fluorescent inks (see C9/L27-50).

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate fluorescent inks into the label and container of modified Stevens, in order to incorporate additional unique identifying information as taught by both modified Stevens and Miller.

6. Claims 31-35, 44, 46, and 53-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over LabDepotInc (Plasticware) VWR (VWR SuperClear Microcentrifuge Tubes).

For claim 44, it is noted that a recitation directed to the manner in which a claimed apparatus is intended to be used does not distinguish the claimed apparatus from the prior art, if the prior art has the capability to so perform. Additionally, LabDepotInc and VWR disclose a container having a body with an opening, a priority indicator (markings on the centrifuge tube are viewed as colored priority indicators) on the body which is visible when a lid (see figure) is in place to close the opening.

For claim 31-35, 44, and 54, LabDepotInc discloses colored plastic microcentrifuge tubes and a method of manufacturing such as yellow tubes (20170-295) and orange tubes (20170-297). VWR discloses that these same tubes have both a body and lid as evidenced by the figure. Additionally, as further evidenced by the figure

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in VWR, the body of the container has etched markings, which are viewed as either indicator bands printed on the body or a label applied to the body.

LabDepotInc does not explicitly disclose that the colored indicator band (or the color of the plastic tubes) has a color of brightness greater than 40% and a saturation greater than 40%. Therefore, as the desired shade of color and container transparency are variables that can be modified, among others, by adjusting said color brightness and saturation, the precise color brightness and saturation would have been considered result effective variables by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed color brightness and saturation cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the color brightness and saturation in the apparatus and method of LabDepotInc to obtain the desired balance between the transparency and the shade of color (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

For claims 46 and 53, the priority indicator/indicator band is either integrated with or is a portion of the label.

For claim 55, the method includes the step of incorporating the indicator band includes applying the label to the body.

For claims 56-57, the method of manufacturing must include the step of incorporating the indicator band to include integrally forming the band with the body of printing (etching) the band on the body.

Response to Arguments

7. Applicant's arguments filed 8/10/09 have been fully considered but they are not persuasive. It is noted that much of applicant's apparent invention and subsequent remarks are directed towards a method of using a priority indicator system, many limitations of which cannot be incorporated into apparatus claims. Arguments to the Stevens reference that were not made moot based on new grounds of rejection were all directed to how the reference differed in the methods employed with the instant *specification*, and are not persuasive for the reasons disclosed above. Applicant asserts that it is unclear from the figure of LabDepotInc what is exactly shown. The examiner respectfully disagrees and further agrees with the assertion made by applicant that these are volume marking etched into the tube. Such etchings are sufficient to meet the claim limitation of a 'label' which extends around a circumference of the tube contrary to applicant's assertion of the contrary.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMESON Q. MA whose telephone number is (571)270-7063. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571)272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael A Marcheschi/
Supervisory Patent Examiner, Art
Unit 1797

JM
November 21, 2009